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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,873	09/05/2003	Shyam S. Mohapatra	USF-182XC1	6872

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SALIWANCHIK LLOYD & SALIWANCHIK
A PROFESSIONAL ASSOCIATION
PO BOX 142950
GAINESVILLE, FL 32614-2950

EXAMINER	
LIETO, LOUIS D	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/655,873	MOHAPATRA ET AL.	
	Examiner	Art Unit	
	Louis D Lieto	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-42* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 2-34, drawn to a method of modulating an immune response comprising administering a pharmaceutical composition comprising a nucleic acid sequence encoding IL-12 to a patient, classified in class 514, subclass 44.

II. Claims 2-34, drawn to a method of modulating an immune response comprising direct administration of a cell containing a nucleic acid sequence encoding IL-12 to a patient, classified in class 424, subclass 93.1.

III. Claims 2-34, drawn to a method of modulating an immune response comprising administering a pharmaceutical composition comprising a nucleic acid sequence encoding IFN-γ to a patient, classified in class 514, subclass 44.

IV. Claims 2-34, drawn to a method of modulating an immune response comprising direct administration of a cell containing a nucleic acid sequence encoding IFN-γ to a patient, classified in class 424, subclass 93.1.

V. Claims 2-39, drawn to a method of modulating an immune response comprising administering a pharmaceutical composition or an expression vector comprising a nucleic acid sequence encoding IL-12 and IFN-γ to a patient, classified in class 514, subclass 44.

VI. Claims 2-34 and 40-42, drawn to a method of modulating an immune response comprising direct administration of a cell containing a nucleic acid sequence encoding IL-12 and IFN-γ to a patient, classified in class 424, subclass 93.1.

Claim 1 links inventions I-VI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 1. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, III, V and II, IV, VI are patentably distinct inventions for the following reasons. In the instant case the different the inventions of groups I, III and V are to methods of administering a pharmaceutical composition comprising a nucleic acid sequence, while the inventions of groups II, IV and VI are to the direct administration of cells comprising a nucleic acid sequence. The nucleic acid of groups I, III and V could be comprised in a plasmid, a virus or

a naked DNA and can be administered topically or orally to a patient in need of. Further, the cell of groups II, IV and VI is structurally different in form and function than the nucleic acid of groups I, III, V and can only be effectively administered by direct injection.

Inventions I, II and III, V are patentably distinct inventions for the following reasons. In the instant case the different inventions of groups I and II are to methods modulating an immune response involving the administration of a nucleic acid encoding IL-12 or of a cell comprising a nucleic acid encoding IL-12, while the inventions of groups III and IV are to methods of modulating an immune response involving the administration of a nucleic acid encoding IFN-γ or of a cell comprising a nucleic acid encoding IFN-γ. IL-12 is a heterodimer that is substantially different in size and amino acid sequence from the homodimer of IFN-γ. Further, Il-12 is produced mainly by B-cells while T-cells and NK cells produce IFN-γ. Neither invention requires the other.

Inventions I, II, III, IV and V, VI are patentably distinct inventions for the following reasons: In the instant case the inventions of groups V and VI are to methods modulating an immune response involving the administration of a nucleic acid encoding IL-12 or of a cell comprising a nucleic acid encoding both IL-12 and IFN-γ, while the different inventions of groups I and II are to methods modulating an immune response involving the administration of a nucleic acid encoding IL-12 or of a cell comprising a nucleic acid encoding IL-12, and the inventions of groups III and IV are to methods of modulating an immune response involving the administration of a nucleic acid encoding IFN-γ or of a cell comprising a nucleic acid encoding IFN-γ. The inventions of groups V and VI require both IL-12 and IFN-γ, while the inventions of groups I and II require only IL-12 and groups III and IV require only IFN-γ. . IL-12 is a

heterodimer that is substantially different in size and amino acid sequence from the homodimer of IFN-γ. Further, Il-12 is produced mainly by B-cells while T-cells and NK cells produce IFN-γ. Because of this the inventions of groups V and VI are substantially different due to the fact that they comprise nucleic acids encoding both IL-12 and IFN-γ.

Furthermore, searching the inventions of groups I, II, III, IV, V and VI together would impose a serious search burden. In the instant case, the search of a method of administering a nucleic acid sequence encoding IL-12, IFN-γ, or the search of a method of administering an isolated cell comprising a nucleic acid sequence encoding IL-12, IFN-γ or both would not be coextensive. As such, it would be burdensome to search the inventions of groups I, II, III and IV together.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention. The inventions of groups I-VI list the following patentably distinct species of antigen:

a) protein

b) peptide

c) glycoprotein

d) carbohydrate

e) lipid

f) glycolipid

g) hapten conjugate

h) recombinant nucleotides

i) killed or attenuated organism

j) toxin

k) toxoid

l) organic molecule

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Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-42 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to

be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Lou Lieto whose telephone number is (571) 272-2932. The examiner can normally be reached on Monday-Friday, 9am-5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy J Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is (703)-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Patent applicants with problems or questions regarding electronic images that can be viewed in the PAIR can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Dr. Louis D. Lieto
Patent Examiner
Art Unit 1632

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER